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December 12, 2007

The Honorable Mary Pat Thynge
United States District Court
844 North King Street
Wilmington, Delaware 19801

VIA ELECTRONIC FILING

Re: Human Genome Sciences, Inc. v. Amgen, Inc. et al., Case No.: 07-526-MPT
Scope of Discovery in a Civil Action under 35 U.S.C. § 146

Dear Judge Thynge:

Plaintiff Human Genome Sciences, Inc. ("HGS") submits this letter pursuant to Your Honor's request on November 21, 2007, and in response to Immunex's December 5, 2007 letter ("December 5 Letter").

HGS filed this action against Immunex under 35 U.S.C. § 146 ("§ 146 action") seeking review of the decision of the Board of Patent Appeals and Interferences ("Board") in Interference No. 105,381 ("the '381 interference"). A civil action under § 146 provides for a complete review of the issues raised during an interference, including the first real opportunity for discovery. Despite this, Immunex seeks to preclude and/or severely limit the Court's ability to examine the issues raised during the interference by limiting the scope and content of discovery. Specifically, Immunex demands that the Court preclude HGS from taking any discovery in this civil action, even though the very purpose of a civil action under 35 U.S.C. § 146—as opposed to a direct appeal to the Federal Circuit under 35 U.S.C. § 141—is to complete the record left by the interference proceeding. No precedent supports constraining HGS's rights under § 146 in the manner urged by Immunex.

Immunex urges the Court to limit the issues that will be heard in this action and the scope of discovery on those issues in a pre-trial scheduling order. This would be improper and premature. First, Immunex argues that the scope of review in a § 146 action is limited to issues *decided* by the Board. Immunex is wrong. The scope of review under § 146 embraces all issues *raised* before the Board, not just those which were decided. Second, the Scheduling Order is not the proper vehicle for limiting the issues to be addressed in this case. The proper time for the Court to rule on the issues to be heard (and the admissibility of evidence on those issues) is after discovery is complete, based on formal motions in limine, *not* in a discovery scheduling order. Third, a framework exists within which Immunex may seek to limit discovery that it believes is outside the scope allowed by the Federal Rules of Civil Procedure. If, during the course of this

action, Immunex disagrees with particular discovery sought by HGS, the Federal Rules provide that Immunex can object to requests when they are made (Fed.R.Civ.P. 34(b)), or move for a protective order (Fed.R.Civ.P. 26(c)). Immunex cites no precedent supporting the pre-emptive and far-reaching limitations that it seeks here. Nor, as described below, is there any factual or practical reason for the Court to limit discovery in this case more than it would in any other civil action.

In this letter, HGS discusses (i) the legal standards for reviewing factual and legal issues in a § 146 action generally; (ii) some of the major issues for this Court to review in this § 146 action; and (iii) why it makes no sense from a case management perspective to decide all discovery issues at this stage of the case, *i.e.*, in a pre-trial scheduling order.

I. The Legal Standards and the Scope of Discovery in a § 146 Action

A fundamental axiom of the United States patent system is that the first party to invent—and only the first party to invent—is entitled to a patent. It is anathema to U.S. patent laws that a later "inventor" be awarded a patent. Thus, when two parties file patent applications containing claims covering the same invention, the U.S. Patent & Trademark Office ("PTO") institutes an administrative proceeding to determine—within the confines of the PTO's rules and procedures—who was the first to invent the subject matter at issue (*i.e.*, to determine "priority" of invention). Once declared, the Board conducts a formal proceeding, managed by an Administrative Patent Judge ("APJ"), pursuant to the Board's rules and regulations. Section 135(a) of the Patent Act, which authorizes the Board to conduct interference proceedings, mandates that priority of invention is to be resolved in every interference: "The Board of Patent Appeals and Interferences shall determine questions of priority of the inventions and may determine questions of patentability." 35 U.S.C. § 135(a) (emphases added).

A. Section 146 Provides for Review of Issues Raised Before the Board

In a § 146 action, the district court can review all issues raised in the original interference proceeding. *Conservolite, Inc. v. Widmayer*, 21 F.3d 1098, 1102 (Fed. Cir. 1994). An issue is "deemed to have been raised for § 146 purposes if the record clearly demonstrates that it was placed before the examiner-in-chief and one or more parties insisted that the issue be resolved in the interference." *Id.* at 1102 (citing *General Instrument Corp. v. Scientific-Atlanta, Inc.*, 995 F.2d 209, 214 (Fed. Cir. 1993)). In fact, when compelling circumstances present themselves, the district court can even consider *entirely new* issues never raised before the Board. *Id.*

Where a broader issue is raised before the Board, evidence related to subsidiary issues can be raised in the § 146 action, even where the subsidiary issue was not raised below. For example, in *Winner Int'l Royalty Corp v. Wang,* 202 F.3d 1340 (Fed. Cir. 2000), the issue of obviousness and the subsidiary issue of commercial success were raised below, but the issue of nexus between the commercial success and the claimed invention was not raised. *Id.* at 1351–52. During the § 146 review, the patent owner was allowed for the first time to present evidence and

arguments on the nexus issue, as this sub-issue was considered to be within the scope of the previously raised issue of obviousness. *Id.*; *see also Estee Lauder v. L'Oreal*, 129 F.3d 588, 592 (Fed. Cir. 1997) (holding that the district court did not abuse its discretion in allowing a party to introduce testing evidence not before the Board because the evidence was relevant to the party's reduction to practice, which was at issue in the appeal).

Immunex's December 5 Letter is confusing and inconsistent regarding the issues that it believes may be raised in a § 146 action. On page 1 Immunex argues that an issue not *decided* by the Board cannot be reviewed under § 146, while on page 4 Immunex acknowledges that an issue presented through a properly filed motion qualifies for § 146 review, even if that issue was not decided by the Board. However, the case law is clear that the scope of review under § 146 includes those issues *raised* before the Board, not just those that were decided. *Conservolite*, 21 F.3d at 1102; *General Instruments*, 995 F.2d at 214. Immunex certainly cites no case supporting the relief it seeks, *i.e.*, that the Court should limit the scope of review to exclude issues raised before but not actually decided by the Board in the context of entering a Scheduling Order.

Immunex cites the case of *Boston Scientific Scimed, Inc. v. Medtronic Vascular, Inc.*, 497 F.3d 1293 (Fed. Cir. 2007) as an example where a district court did not consider a new issue. However, that holding is inapplicable here. In *Boston Scientific*, the key issue during the interference was whether a party was entitled to benefit of a foreign application under 35 U.S.C. § 119. After the Board denied benefit, the losing party filed a § 146 civil action, whereupon the parties stipulated that the sole issue was whether the Board erred in denying foreign benefit. But during the § 146 action, the losing party also tried to inject entirely new legal theories as to why it should be able to claim foreign benefit, *i.e.*, constructive trust and equitable assignment, which were never presented to the Board and which are not necessary to any element of a § 119 analysis. *Id.* at 1298. The Federal Circuit affirmed that the district court was not required to consider these newly-raised issues.

B. Section 146 Allows Discovery to Augment the Limited Evidentiary Record Developed Before the Board

At the conclusion of an interference proceeding, the Patent Act offers the parties two distinct options for judicial review of the Board's decisions: A party may seek review of the Board's decisions directly by the U.S. Court of Appeals for the Federal Circuit pursuant to 35 U.S.C. § 141, or the party may seek review in a civil action by a district court pursuant to 35 U.S.C. § 146.

During an interference, discovery is relatively limited. The Board's rules and precedent are geared towards making interferences "speedy and inexpensive" proceedings, and accordingly, the Board's rules and precedent greatly limit discovery in interference proceedings.

While limited depositions are permitted,[1] neither discovery requests, interrogatories, requests for admissions, nor third-party subpoenas are permitted, absent a showing that such discovery is "in the interests of justice." 37 C.F.R. § 41.150(c). In practice, meeting this burden is difficult, and therefore obtaining any discovery in an interference proceeding is rare.[2] The effects of limited discovery in an interference are tempered by the availability of full discovery in a § 146 review:

> Limited administrative discovery is consistent with the policy directive that the patent interference rules must be construed to secure a just, speedy, and inexpensive determination of every interference.... It is also consistent with the availability of an evidentiary trial, 35 U.S.C. 146, to review administrative interference decisions.

Johnston v. Beachy, 60 U.S.P.Q.2d 1584, 1587 n.4. (B.P.A.I. 2001).

The fundamental purpose of a § 146 action—unlike a § 141 appeal to the Federal Circuit, which reviews the Board's decision exclusively based on the limited record of the interference proceeding—is to allow the parties to complete the record by taking further discovery. Not only does a § 146 action provide that either party can submit the entire interference record into the civil action, but also that the parties have the *right* to additional discovery:

> Any party to an interference dissatisfied with the decision of the Board of Patent Appeals and Interferences on the interference may have remedy by civil action.... In such suits the record in the Patent and Trademark Office shall be admitted on motion of either party ... without prejudice to the right of the parties to take further testimony. [emphases added].

35 U.S.C. § 146. There are no statutory restrictions on the discovery procedure in a § 146 civil action, and the Federal Rules of Civil Procedure apply, allowing interrogatories, document requests, admissions, depositions, expert reports, and so on.

Section 146 authorizes the district court to allow all discovery within the confines of Federal Rule of Civil Procedure 26, and virtually all § 146 cases, including those cited by

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[1] If a party submits a declaration, its adversary has the right to depose the declarant. 37 C.F.R. § 41.157.

[2] The Board will not even allow an interference party to obtain highly relevant documents involving its own priority case from third parties holding such documents, *e.g.*, documents from laboratories contracted to conduct assays related to the discovery of the invention. In the present case, the Board repeatedly refused to allow HGS to obtain its *own* documents in the possession of the University of Michigan relating to research conducted pursuant to a collaborative research agreement.

Immunex, have allowed liberal discovery.[3] Immunex points to no case where a district court was reversed for allowing discovery in a § 146 action. Immunex also conflates the constraints on admissibility with those on discoverability. Courts generally wait until the pre-trial hearing to decide what discovery will be *admissible*, based on the issues to be tried. The scope of the new evidence admitted during the trial is determined based on *admissibility* of such evidence, not on a prior adjudication regarding *discoverability*. As in all civil actions, parties to a § 146 action are entitled to obtain discovery of all relevant evidence, as well as evidence "reasonably calculated to lead to the discovery of admissible evidence," even if such evidence is not admissible at trial. Fed.R.Civ.Proc. 26(b)(1).

To support the discovery limitations that it seeks, Immunex mischaracterizes the law. For example, Immunex implies that a party is precluded from presenting any evidence not included within the interference record if the party did not exercise diligence in seeking that evidence during the interference proceeding. *See* December 5 Letter at 5 (Part C) and 7. As an initial matter, the cases cited by Immunex addressed the issue of admissibility, not discoverability. As explained at length by the court in *University of Massachusetts v. Roslin Inst.*, 437 F. Supp. 2d 57 (D.D.C. 2006), there is a fundamental difference between admissibility and discoverability. *Id.* at 61–62. In that case, the Court rejected the defendant's attempts to tightly limit discovery to the issues raised below, noting the liberal scope of discovery in § 146 actions. *Id.* at 62. The controlling law on this issue was set forth by the Federal Circuit in *Winner*. In *Winner* the Federal Circuit set forth that the admissibility of evidence at trial is reviewed for an abuse of discretion, and affirmed that it was not an abuse for the district court to admit new testimony and evidence with respect to a subsidiary issue (nexus) in light of the fact that the issue of commercial success was raised to the Board. 202 F.3d at 1351. In affirming this decision, the Federal Circuit looked only at the *relevance* of the evidence, and did not require any showing of diligence in obtaining the evidence, as Immunex now claims the law requires.

Immunex mischaracterizes the holding of *Cell Genesys, Inc. v. Applied Research Sys.*, 499 F. Supp.2d 59, 71 (D. Mass. 2007). In that case, the district court allowed full discovery. *Id.* at 61. After two years of fact and expert discovery and after a pre-trial hearing, one party to the § 146 action filed a motion in limine to exclude certain evidence never presented to the Board during the interference. Although the district court ultimately declined to admit the disputed evidence at trial, it never indicated that discovery on the underlying issue during the § 146 action was improper. In denying admissibility, the court recognized that the law on this point was open

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[3] The only cases cited by Immunex where discovery was limited were *Brunswick Corp. v. Riegel Textile Corp.*, 627 F. Supp. 147 (N.D. Ill. 1985) and *Stamicarbon v. Chemical Construction Corp.*, 355 F. Supp. 228, 234 (D.Del. 1973). But in those cases, the district judge had already ruled *in limine* not to exercise his discretion to review the issues in those cases. *Brunswick* is further distinguishable because the party tried to seek discovery on derivation—the allegation that the named inventor obtained the idea from someone else—even though the Board Rules expressly precluded the party from raising derivation during the interference. *See* 37 C.F.R. § 1.633(a)(2) (holding that a preliminary motion may not be based on derivation from an opponent).

to interpretation. *Id.* at 69 (citing *General Instrument*, 995 F.2d at 214 (stating that "we again have no occasion to decide whether 'a district court may properly restrict the admission of testimony on an issue raised before the [B]oard.'")). The district court in *Cell Genesys* has certified this issue for interlocutory appeal.

C. Review in a § 146 Action

Because the record in a § 146 action contains both the existing evidentiary record from the interference proceeding (which was before the Board) as well as new evidence (which was not before the Board), the Federal Circuit has described the § 146 action as a "hybrid of an appeal and a trial *de novo*." *Winner*, 202 F.3d at 1345. This hybrid nature creates the following burdens of proof.

If any testimony is submitted at trial on a factual issue raised during the interference, the district court reviews the issue *de novo*. *Winner*, 202 F.3d at 1347; *Genentech, Inc. v. Chiron Corp.*, 220 F.3d 1345, 1351 (Fed. Cir. 2000). Similarly, if any non-testimonial evidence is submitted on a factual issue, the issue is tried *de novo*. *Winner*, 202 F.3d at 1347. Only if no new testimony or evidence is submitted on an issue is deference paid to the Board's fact finding. *Id.* For legal determinations, the district court always reviews the Board's decision *de novo*. *Boston Scientific*, 497 F.3d at 1296. This Court makes its own procedural determinations. The cases that Immunex cites, which concern § 141 review, do not alter this fundamental principle.

II. The Issues and Relevant Discovery to This Civil Action

As early as 1994, HGS was actively searching for polypeptides (*i.e.*, proteins) and DNA sequences useful for new medical treatments and diagnostics. Of particular interest to HGS were novel "death receptors," proteins expressed on the surface of cells that induce programmed cell death, or apoptosis. Such receptors can be targeted to modulate cell death to treat diseases such as cancer and HIV infection. Among the death receptors identified by HGS by the end of 1996 were receptors designated DR3 and DR4. In December 1996, HGS researchers identified yet another death receptor, called DR5, which is the subject of the HGS patent application at issue here. HGS filed Provisional Application 60/040,846 on March 17, 1997, another Provisional Application 60/054,021 on July 29, 1997, and a year later, HGS filed U.S. Utility Application No. 09/042,583 ("the '583 application"), which claims benefit to the original provisional applications. The PTO declared the '381 interference between the '583 application and a patent assigned to Immunex.[4] This § 146 action was filed to review the decisions of the Board in that proceeding.

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[4] The PTO actually declared four separate interference proceedings involving HGS patents and/or pending patent applications, three involving Immunex, and another involving Genentech. Two of those interferences are still pending, whereas the third concluded on November 20, 2007, and a § 146 action was filed in the District Court of Delaware on November 30, 2007, asking for review of the Board's decision in that interference.

Collectively, HGS's complaint and Immunex's counterclaims ask the Court to review at least the following illustrative and non-limiting issues that were raised during the interference.

A. The Issue of Priority Is Properly Subject to § 146 Review

Priority is subject to review in this action. Immunex's arguments that the Board chose not to resolve priority is irrelevant because issues that were properly raised in a motion, even if not decided by the Board, are subject to Section 146 review. In its letter, Immunex acknowledges that "[f]or an issue not decided by the Board to qualify for Section 146 review, a party must fully present the issue through a properly filed motion during the interference." *See* December 5 Letter at 4. There is no dispute that HGS fully presented the issue of priority. HGS properly filed a motion on priority (Motion 7). HGS had previously obtained the Board's permission to file that motion and to supplement it. The issue of priority is subject to review in this action.

None of the cases cited by Immunex, including *Boston Scientific*, mandate a different result. HGS is seeking review on priority based on legal theories set forth in its Motion 7. Accordingly, this Court has jurisdiction to hear the issue of priority—a fact which Immunex has not disputed.

In an attempt to get the Court to decline to exercise its jurisdiction, Immunex argues that the Court should exercise discretion and ignore the issue of priority. However, Immunex provides no compelling reason for the Court to do so, especially at this early stage in the case. Immunex intimates that if this Court reverses the Board's other rulings, it would be more efficient to have the Board conduct another administrative phase of proceedings. But if the Court chose this option, the parties would be forced to proceed through yet another administrative phase with limited discovery, and this Court likely would be forced to allow more discovery, and hold another trial, after that phase was completed. The burdens on the Court and the parties would not be justified, nor would the delay in the disposition of this case be justified.

Immunex concedes that discovery is appropriate for priority, assuming that it qualifies for § 146 review (which, as set forth above, it does). *See* December 5 Letter at 6.

B. Immunex Acknowledges That the Remaining Issues Are Subject to § 146 Review

Immunex does not dispute that the review under 35 U.S.C. § 146 in this case includes a review of both HGS's and Immunex's claims of benefit, the unpatentability of both HGS's and Immunex's claims under § 102(e), substitution of the count, and motions to exclude evidence.[5] Nor does Immunex dispute that it may have evidence in its possession that is reasonably

[5] Though not in its counterclaim, Immunex has stated that it will seek review of the denial of its motion to designate HGS's claims 46, 55, 63, 64, 110 and 118 as corresponding to the count.

calculated to lead to the discovery of admissible evidence on the issue of benefit, or is otherwise relevant to the issues on review. Immunex instead argues that there is no discovery appropriate for any of these issues.

For example, Immunex argues that the issue of benefit relates solely to the disclosure of a priority application to one of ordinary skill in the art, and, therefore, there is no relevant discovery related to this issue. *See* December 5 Letter at 8. This ignores the fact that entitlement to benefit is based on numerous other legal principles, such as written description (a question of fact) and enablement (a question of law based on underlying fact). Federal Circuit case law supports the basic proposition that factual evidence is relevant to each of these inquiries. *See Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473, 1478 (Fed. Cir. 1988) (testimony of inventor relevant to written description inquiry); *Purdue Pharma L.P. v. Faulding, Inc.*, 230 F.3d 1320, 1324–25 (Fed. Cir. 2000) (factual testimony relevant to written description inquiry); *Enzo Biochem v. Calgene*, 188 F.3d 1362, 1372–73 (Fed. Cir. 1999) (evidence of failures of inventors after filing date); *AK Steel Corp. v. Sollac*, 344 F.3d 1234, 1243–44 (Fed. Cir. 2003) (non-enablement based on fact testimony and evidence obtained from patentee). Accordingly, for the issue of benefit, discovery from Immunex related to the work done in this field by its scientists, including the work leading to the filed patent applications and their subsequent work, is appropriate under Rule 26. Further, in its claims for benefit, Immunex goes beyond the patent applications and invokes the theory of "inherency." *See* December 5 Letter at 8–9. Full fact discovery related to the compounds which Immunex contends "inherently" have certain properties is likewise appropriate and necessary.

As a further example, Immunex states that the issue of unpatentability under § 102(e) relates solely to the disclosure of the priority applications to one of ordinary skill in the art. This completely ignores the fact that anticipation is a question of fact. As the Court is well aware, discovery with respect to the subject matter of an alleged anticipatory reference is not only permissible, it is ubiquitous in patent litigation, and a § 146 action should be no different. Discovery into the origins of the patent applications which Immunex contends constitute anticipatory art is relevant to this issue, including the work done by its scientists and others at Immunex related to the subject matter disclosed in these patent applications.

So long as the information sought is relevant to one of the issues to be reviewed, it is appropriate. Fed.R.Civ.P. 26(b)(1) ("Parties may obtain discovery regarding any matter, not privileged, that is relevant to a claim or defense of that party.... Relevant information need not be admissible at the trial if the discovery appears reasonably calculated to lead to the discovery of admissible evidence."). Issues of discoverability are typically raised and resolved in civil actions through motions to compel and protective orders under Federal Rules 26(b) and 26(c). None of the cases cited by Immunex stand for the proposition that discovery in a § 146 action is any different. To the extent that this Court wishes to consider specific issues of discovery now, HGS respectfully contends that such issues should be briefed in a motion for a protective order by Immunex.

III. Case Management for This Civil Action

It is not an overstatement to say that Immunex's December 5 Letter should be restyled a "Combined Motion to Preclude All Discovery and Motion in Limine to Limit the Evidence Presented at Trial." To so dramatically limit discovery, and even define the entire course of conduct for the eventual trial of this action, prior to entry of a scheduling order, would be improper and is an invitation to error. Immunex is in effect requesting that Your Honor decide what issues the Trial Judge should consider at trial, *i.e.*, what issues were raised in the interference proceeding, as well as the evidence that will be available to the Trial Judge in considering those issues. As discussed above, there are multiple issues at play in this action, and Immunex's requested restriction on discovery is not supported by statute or case law. Moreover, limiting the issues at this juncture would be manifestly unfair.

HGS asks this Court to enter a scheduling order that is consistent with the scope of § 146, which allows discovery concerning any issue raised before the Board. As in any other matter, this Court should permit the parties to propound discovery requests, and evaluate the scope of discovery on an issue-by-issue basis if, and when, a dispute arises. The Federal Rules of Civil Procedure provide all the mechanisms for both Immunex and HGS to object to discovery requests, and even to request a protective order. Under a Fed.R.Civ.P. 26(c) protective order, a party must show that justice requires the preclusion of particular discovery in order "to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense." Despite the fact that Immunex is effectively requesting a protective order in the Court's initial scheduling order, Immunex has not met its burden for such a limitation on discovery. After the close of fact and expert discovery, the issue of what evidence should be presented at trial should be handled by the Trial Judge via motions in limine and at the pretrial conference, as in any other action.

Respectfully,

/s/ John G. Day

John G. Day

JGD/nml
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